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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,443

12/20/2006

Hitoshi Kotani

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BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,443	Applicant(s) KOTANI ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69 and 73-92 is/are pending in the application.
- 4a) Of the above claim(s) 73-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69 and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment and remarks filed February 18, 2009, are acknowledged and entered. Claims 69 and 73-92 are pending. Claims 69 and 92 are under examination. Claims 73-91 are withdrawn from consideration, being drawn to non-elected subject matter.

Claims Summary and Interpretation

2. The claims are drawn to a method for inhibiting tumor cell growth in an animal by administering a composition that consists essentially of a hemagglutinating virus of Japan (HVJ) viral envelope (HVJ-E). The transitional phrase "consists essentially of" indicates that the composition contains HVJ-E, and no other component that inhibits tumor cell growth. The composition may contain any other component that does not inhibit tumor cell growth.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 92 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The specification fails to support the limitation in claim 92 with regard to enhanced tumor immunity as a result of administering a composition consisting essentially of HVJ-E. Applicant points to examples 5 and 6, demonstrating that HVJ-E induces IL-12 and IL-16 in dendritic cells, and inhibits regulatory T cells. The Office has considered examples 5 and 6, however, the conclusion that anti-tumor immunity is enhanced is not supported by the examples. Applicant's conclusion of enhanced anti-tumor immunity was not appreciated at the time of filing this application. The specification merely reports the effect of HVJ-E on certain cell types, but fails to draw conclusions of enhanced immunity.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 69 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneda (EP 1170363 A1, filed in IDS of 12/20/06). The claims are summarized above. Kaneda discloses virus envelope vectors for gene transfer, comprised of inactivated HJV particles (see abstract and paragraphs [0011-0012]). Kaneda discloses that the vector is capable of gene transfer into a broad range of in vivo tissue, including cancer tissue (see paragraph [0012]). Although Kaneda does not teach that the vectors are effective for enhancing an immune response or for inducing an antitumor response, the structural limitations of the claims are met by Kaneda's HVJ viral vector because it comprises viral envelope protein. Therefore, any

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functional properties of the instant vector are expected to be present in Kaneda's vector, thus the method is expected to accomplish the same functions instantly claimed.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that Kaneda discloses the use of HVJ-E as a gene transfer vector for introducing a foreign gene, thus the construct comprises more than HVJ-E because it also comprises a foreign gene. For this reason, Applicant argues that Kaneda's disclosure is outside the scope of the instantly claimed method that uses a composition consisting essentially of HVJ-E as an active ingredient.

In response to Applicant's arguments, the transitional phrase "consists essentially of" indicates that the composition contains HVJ-E as an active ingredient for inhibiting tumor cell growth in an animal, and no other component is present that inhibits tumor cell growth. The composition may contain any other component that does not inhibit tumor cell growth. Kaneda discloses an inactivated HVJ virus envelope that can serve as a vector for virtually any gene of interest (see Figure 6). An HVJ-E was constructed that contains green fluorescent protein (GFP) (see Example 7 on page 8). Even though the HVJ-GFP construct is not taught for use in a method of inhibiting tumor cell growth, the example is illustrative of the broad range of genes that can be inserted into Kaneda's method. The genes of interest are not limited to any class of therapeutics, that is, the genes are not limited to those that inhibit tumor cells. Thus, the administration of Kaneda's construct (HVJ inactivated envelope with any gene of interest) anticipates the instant invention because the gene of interest is not limited to those that inhibit tumor cell growth, rendering the gene of interest not an active ingredient. Therefore, the invention remains anticipated by Kaneda.

Conclusion

5. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648